DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 11, 2015

Surefire Medical, Inc.
c/o Mark Job
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K143588
Trade/Device Name: Surefire Infusion System 021
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: December 17, 2014
Received: December 18, 2014

Dear Mr. Job:

This letter corrects our substantially equivalent letter of January 12, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Surefire Infusion System 021

Indications for Use *(Describe)*
The Surefire Infusion System 021 is intended for use in angiographic procedures.
It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY (DATE PREPARED: OCTOBER 28, 2014)

Device Name
Surefire Infusion System 021

Manufacturer Name and Address
Surefire Medical, Inc.
6272 W. 91st Avenue
Westminster, CO 80031
Owner Operator Number: 10038066

Submitter Contact Information
Surefire Medical, Inc.
6272 W. 91st Avenue
Westminster, CO 80031
Contact: Lynne Aronson, VP Regulatory Affairs and Quality Assurance
Phone: 303-426-1222 Fax: 303-426-1223

Common, Classification & Proprietary Names

Common Name:	diagnostic intravascular catheter
Classification Name:	diagnostic intravascular catheter
Proprietary Name:	Surefire Infusion System 021
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Classification Regulation:	21 CFR 870.1200
Product Code:	DQO

Predicate Device
- Surefire Infusion System K121677

Device Description
The Surefire Infusion System 021 is a 0.021" lumen coaxial microcatheter with the Surefire Expandable Tip at the distal end. It has an outer sheath to facilitate expanding and collapsing the Surefire Expandable Tip. The Surefire 021, serves as the conduit for physician-specified agents such as contrast agents, flush solutions, and embolic beads. It is compatible with standard 0.018" guide wires, infusion syringes, rotating hemostatic valves (RHVs/Tuohy Borsts), and embolic hydrogel particles 500μm or less in size and glass microspheres 110μm or less in size. The Surefire 021 has a Teflon inner liner to provide a lubricious surface for passage of physician-specified agents and other accessory devices. The device is hydrophilically coated. The soft, pliable, funnel-shaped Surefire Expandable Tip is sized for use in vessels of 1.5mm to 4 mm.

There are two radiopaque markers located just proximal and distal to the Surefire Expandable Tip. The Tip can be expanded or collapsed up to 3 times for re-positioning during an interventional procedure by simply retracting or advancing the inner microcatheter while holding the outer sheath stationary. When expanded, the Expandable Tip is designed to improve infusion efficiency of compatible embolic agents while maintaining antegrade flow in various size vessels.

The Surefire Infusion System 021 is provided sterile (EtO) for single patient use.

Indications for Use

The Surefire Infusion System 021 is intended for use in angiographic procedures.
It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Biocompatability Testing

Biocompatibility testing of the patient-contact materials used in the construction of the catheter was performed in accordance with ISO 10993-1 for an external communicating device in contact with circulating blood with a limited duration of less than 24 hours. The following testing was conducted in accordance with GLP by NAMSA (Northwood, OH).

The following biocompatibility testing was conducted on the Surefire Infusion System (K121677) which are constructed of the same materials as the Surefire Infusion System 021. Therefore, the biocompatibility test requirements for the Surefire Infusion System 021 were met by leveraging previously completed biocompatibility testing.

Category	Standard	Test Method
Cytotoxicity	ISO 10993-5	Cytotoxicity Study Using the ISO Elution Method – 1x Minimal Essential Media Extract
Sensitization	ISO 10993-10	ISO Maximization Sensitization Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Maximization Sensitization Study – Extract – Sesame Oil, NF Extract
Irritation or Intracutaneous Reactivity	ISO 10993-10	ISO Intracutaneous Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Intracutaneous Study – Extract – Sesame Oil, NF Extract
Systemic Toxicity	ISO 10993-11	ISO Systemic Toxicity Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Systemic Toxicity Study – Extract – Sesame Oil, NF Extract
		Pyrogen – Material Mediated – 0.9% Sodium Chloride Solution Extract
Hemocompatability	ISO 10993-4	ASTM Hemolysis – CMF-PBS Extract
		C3a Complement Assay – Normal Human Serum Extract
		SC5b-9 Complement Assay – Normal Human Serum Extract
		Coagulation – ASTM Partial Thromboplastin Time

Additionally, testing for thrombogenicity was performed on the Surefire Infusion System 021 Catheter as a part of an Animal Study.

The results of all of the biocompatibility testing did not indicate any significant biological reaction that would affect the patient due to contact with the materials used in the device construction.

Performance Testing

Design verification testing was performed which demonstrated that the Surefire Infusion System 021 meets its specified performance requirements, and is equivalent to the performance of the predicate device. Testing included visual and dimensional inspection, and tests for hydrophilic coating lubricity and wear, particulates, high pressure injection (burst pressure), tensile strength, kink resistance, torque resistance, trackability, infusion agent compatibility, embolic agent compatibility, antegrade flow and infusion efficiency.

The results of testing demonstrated that the Surefire Infusion System 021 meets its specifications and is comparable in mechanical strength and performance to the predicate Surefire Infusion System.

Animal Testing

An animal study was performed to assess the comparative acute performance of the Surefire Infusion System 021to the predicate device, as defined by physician's in a simulated clinical environment. The Surefire Infusion System 021was found to have acceptable performance. Additionally, the Surefire Infusion System 021was found to have comparable performance to the predicate device.

Substantial Equivalence

The Surefire Infusion System 021is substantially equivalent in intended use, design, and technology/principles of operation to the predicate.

Comparative Summary: Design / Technological Characteristics

The Surefire Infusion System 021 and predicate device are coaxial microcatheters with the Surefire Expandable Tip at the distal end. Both infusion systems have an outer catheter to facilitate expanding and collapsing the Surefire Expandable Tip.

The Surefire Infusion System 021 and the predicate device are constructed of similar materials utilizing similar construction and manufacturing processes.

The Surefire Infusion System 021 and predicate device have similar dimensions, with the Surefire Infusion System 021 having smaller outer and inner diameters. Both catheters are 120 cm in length. Due to the smaller inner lumen dimension, the maximum sized embolic beads that are compatible with the Surefire Infusion System 021 are smaller than with the predicate device.

The Surefire Infusion System 021 and predicate device are provided in identical packaging, sterilized by ethylene oxide, and labeled for single use only.

Comparative Summary: Indications for Use

The Surefire Infusion System 021 has the same indications for use as the predicate device. Both devices are intended for use in angiographic procedures to deliver radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Comparative Summary: Performance

Animal and bench performance test data demonstrate that the Surefire Infusion System 021 performance is comparable to the predicate device.

In summary, the Surefire Infusion System 021 is substantially equivalent in intended use, design, and technology/principles of operation to the predicate. Animal and bench performance test data demonstrate that the Surefire Infusion System 021 performance is comparable to the predicate device. Differences between the devices do not raise any issues of safety or effectiveness.